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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,692	11/16/2000	Kuo-Fen Lee	D6233CIP	5372
7590 DAVID L PARKER FULBRIGHT & JAWORSKI LLP 600 CONGRESS AVENUE SUITE 2400 AUSTIN, TX 78701		02/06/2009		
EXAMINER				
BUNNER, BRIDGET E				
ART UNIT		PAPER NUMBER		
1647				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/714,692

**Applicant(s)**

LEE ET AL.

**Examiner**

Bridget E. Bunner

**Art Unit**

1647

**Period for Reply** -- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on the amendment of 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-23 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-23 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-884)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

Claims 20-23 and 28-30 are pending and under consideration in the instant application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Villalona-Calero et al. (Ann Oncol 9: 71-77, 1998). The basis for this rejection is set forth in the Examiner's Answer of 07 November 2005 and the Office Actions of 14 May 2008, 15 November 2007, 04 March 2004, and 21 October 2003.

The claims remain rejected for reasons of record, as affirmed by the Board of Patent Appeals and Interferences in the decision dated 31 March 2006.

Applicant's arguments (14 October 2008), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) At page 5 of the Response, Applicant argues that the Examiner has failed to provide a technical reasoning to support a conclusion that the methods for cancer treatment used by Villalona-Calero involve determining whether angiogenesis has been inhibited in said individual, as specified by the claims. Applicant asserts that based on this discovery by the present inventors, it is now known that CRFR2 agonists can inhibit endogenous angiogenesis and specific tumors can now be targeted through administration of a CRFR2 agonist. Applicant

contends that Villalona-Calero does not suggest the possibility of inhibition of angiogenesis by a CRFR2 agonist and cites *in re Robertson* (169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) to emphasize that that inherency may not be established by probabilities or possibilities. At page 6, the top of page 7, and the middle of page 8 of the Response, Applicant submits that there is no explicit or implicit teaching in Villalona-Calero to support the idea that angiogenesis is altered by hCRF.

Applicant's arguments have been fully considered but are not found to be persuasive. Villalona-Calero teaches administering a corticotropin releasing factor 2 (CRFR2) agonist, specifically human corticotropin releasing factor (CRF), to individuals. Specifically, Villalona-Calero teaches that human patients with primary or secondary brain tumors with evidence of edema are administered CRF intravenously, by continuous infusion (pg 72, col 1, first and second full paragraphs). Additionally, since Villalona-Calero administer human CRF, a CRFR2 agonist, to the same subject population and the same tissues as recited in the claims, inhibition of angiogenesis must have been inherently occurring in the prior art of Villalona-Calero (*Ex parte Novitski*, 26 USPQ2d 1389 (BPAI 1993); see also *Integra LifeSciences I Ltd. V. Merck KGaA*, (DC SCalf) 50 USPQ2d 1846)). The disclosure of Villalona-Calero fully meets the terms of the claimed method because a CRFR2 agonist (corticotropin releasing factor) inherently possesses angiogenesis-inhibiting activity. A compound and all of its properties are inseparable; they are one and the same thing and simply stating a new property of CRF does not render the claimed method of inhibiting angiogenesis of the instant application free of the art (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971); *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978)). Furthermore, "[p]roducts of identical

chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (see also MPEP 2112.01 (II)). The broad method steps claimed in the instant application are the same as the steps disclosed in Villalona-Calero. Applicant’s assertion that CRFR2 agonists, such as human CRF, inhibit angiogenesis in a target tissue was already inherent in Villalona-Calero. If Villalona-Calero would have attempted to measure the effect of human CRF on angiogenesis in brain tumor tissue, they would have uncovered it. Thus, Villalona-Calero anticipates the claimed invention of the instant application. Furthermore, inherent anticipation does not require that one of ordinary skill in the art recognize an inherent feature in a prior art disclosure (*Schering Corp. v. Geneva Pharmaceuticals Inc.*, 67 USPQ2d 1664 (CAFC 2003); *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)).

(ii) At the middle of page 6 of the Response, Applicant states that as would be appreciated by one of skill, there exists a myriad of possible reasons that an acute effect might be observed on the microvasculature. Applicant indicates that as would be appreciated by one of skill, a reduction of brain edema after administration of a compound for only 24 hours would not be assumed to imply an alteration in angiogenesis. Applicant contends that these results would suggest to one of skill that some acute anti-edematous effect (not alteration in the growth of cells) would be the pharmacological function. At page 7 of the Response, Applicant argues that some acute action on the microvasculature may be affecting water content, but does not give any

indication as to what action hCRF may have on the microvasculature. Applicant concludes that the acute effects observed in Villalona-Calero would suggest to one of skill that angiogenesis is not occurring.

Applicant's arguments have been fully considered but are not found to be persuasive. Villalona-Calero discloses that hCRF has significant anti-edematous action, which appears to be independent of the release of adrenal steroids and mediated by a direct effect on endothelial cells (page 71, abstract; emphasis added by Examiner). Villalona-Calero also state on page 76 (column 2, 2nd full paragraph) that "[t]he mechanisms for hCRF-induced hypotension is not known". Since Villalona-Calero administers human CRF, a CRFR2 agonist, to the same subject population and the same tissues as recited in the claims, inhibition of angiogenesis must have been inherently occurring (*Ex parte Novitski*, 26 USPQ2d 1389 (BPAI 1993); see also *Integra LifeSciences I Ltd. V. Merck KGaA*, (DC SCalf) 50 USPQ2d 1846)). Again, inherent anticipation does not require that one of ordinary skill in the art recognize an inherent feature in a prior art disclosure (*Schering Corp. v. Geneva Pharmaceuticals Inc.*, 67 USPQ2d 1664 (CAFC 2003); *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)).

(iii) At the bottom of page 6 of the Response, Applicant states that Villalona-Calero do not monitor angiogenesis with MRI scans. Applicant argues that the Action's assertion that an MRI scan could have separately been used to try to evaluate angiogenesis is irrelevant to the question of whether the MRI scans were used to evaluate angiogenesis. Applicant submits that this argument in the Action is improperly based on hindsight and/or the possibility that the tool used

in Villalona-Calero would have been separately used for a different purpose or in a different way.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, Villalona-Calero utilizes MRI scans to determine the degree of edema in patients before and after the completion of the infusion of hCRF (page 72-73; abstract). Thus, the broad method steps claimed in the instant application are the same as the steps disclosed in Villalona-Calero. Applicant's assertion that CRFR2 agonists, such as human CRF, inhibit angiogenesis in a target tissue was already inherent in Villalona-Calero. If Villalona-Calero would have attempted to measure the effect of human CRF on angiogenesis in brain tumor tissue, they would have uncovered it.

(iv) At the bottom of page 7, Applicant argues that evaluating changes in the water content of a tumor as performed in Villalona-Calero is distinct from determining whether angiogenesis has been inhibited according to the instant claims. Applicant also asserts that cancers may vary greatly in their responses to therapeutic agents. Applicant submits that it is feasible that the specific cancer tested in Villalona-Calero may not have exhibited significant changes in angiogenesis during the acute timeframe of administration, but rather that changes in water content of the tumors are due to some other effect of hCRF administration.

Applicant's arguments have been fully considered but are not found to be persuasive. First, arguments of counsel alone cannot take the place of evidence in the record. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the

record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

Furthermore, since Villalona-Calero teaches administering human CRF, a CRFR2 agonist, to the same subject population and the same tissues as recited in the claims, inhibition of angiogenesis must have been inherently occurring (pg 72, col 1, first and second full paragraphs). It is noted that "[A]fter the [examiner] establishes a *prima facie* case of anticipation based on inherency, the burden shifts to appellant to 'prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986) (quoting *In re Swinehart*). In the instant application, Applicant does not establish a difference between the claimed invention and prior art method. Nothing in the specification or claims provides any details regarding the effective amount of CRFR2 agonist for administration or in any other way distinguishes the claimed method from the prior art. As mentioned in the BPAI decision of 31 March 2006 (page 6), "[i]t is a general rule merely discovering and claiming a benefit of an old process cannot render the process again patentable" (*In re Woodruff*, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376, 58 USPQ2d 1508, 1514 (Fed. Cir. 2001).

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting angiogenesis in a human individual with cancer comprising administering a CRFR2 agonist to said individual, does not reasonably provide enablement for a method of inhibiting angiogenesis in a human individual with a pathophysiological condition which is not cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 5-8 of the previous Office Action (14 May 2008).

Applicant's arguments (14 October 2008), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) At page 9 of the Response, Applicant argues that the present specification provides direct biological evidence that CRFR2 is critically involved in angiogenesis in all tissues tested and refers to abstract and Example 16. Applicant argues that *in vitro* evidence is routinely used to support methods for *in vivo* therapies. Applicant points out that § 112 does not require an actual reduction to practice.

Applicant's arguments have been fully considered but are not found to be persuasive. Although Applicant needs to not actually have reduced the invention to practice prior to filing the application, the lack of a working example is only one factor to be considered, especially in a

case involving an unpredictable art (MPEP § 2164.02). As discussed in the previous Office Action, the specification teaches that angiogenesis is stimulated in CRFR2 null mutant mice because CRFR2 null mutant mice appeared to exhibit an increase in the size and number of blood vessels in various tissues" (Example 16; page 48, lines 20-21). The specification also indicates that since the CRFR2 receptor and its activity have been localized within the endothelial cell layer of blood vessels, it is hypothesized that CRFR2 may play a role in regulating angiogenesis" (page 49, lines 4). However, the prophetic procedure outlined in the specification for inhibition of angiogenesis in a target tissue by administration of a CRFR2 agonist (page 8, lines 6-10; page 25, lines 19-21; page 26, lines 1-4) is not disclosed in a manner such that one skilled in the art could inhibit angiogenesis in a target tissue without undue experimentation. For instance, there is little guidance to indicate that the administration of a CRFR2 agonist inhibits angiogenesis in individuals with any number of diverse disease states that require inhibition of angiogenesis. The limited amount of guidance in the specification is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. The prophetic method disclosed in the instant specification may not necessarily inhibit angiogenesis in an individual having a pathophysiological condition which is not cancer and undue experimentation would be required by the skilled artisan to determine such. The specification also does not provide any *in vitro* examples that are art recognized model systems for *in vivo* therapies. Additionally, the Examiner's indication of the absence of a working example is only one facet of the Wands factors, which were provided in the previous Office Action (14 May 2008).

(ii) At the bottom of page 9 of the Response, Applicant asserts that the argument provided in the Action ("possibly, mechanisms driving the angiogenic cascade are differentially regulated depending on the disease pathology") is irrelevant to the claimed invention because it appears to assume that an equivalent mechanism of arriving at a disease state must be exhibited in order to achieve some benefit from a therapeutic. Applicant states that a myriad of different underlying biological phenomena or causes may contribute to the emergence of a disease state which can be treated by a therapeutic which may function via a pathway unrelated to the emergence of the disease state. Applicant submits that the inhibition of angiogenesis (e.g., by a CRFR2 agonist) may be therapeutically utilized to treat a variety of disease states which would benefit from an inhibition of angiogenesis.

Applicant's arguments have been fully considered but are not found to be persuasive. Regarding Applicant's argument that inhibition of angiogenesis (e.g., by a CRFR2 agonist) may be therapeutically utilized to treat a variety of disease states which would benefit from an inhibition of angiogenesis, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

Contrary to Applicant's assertion, the argument provided in the previous Office Action (citing Griffioen et al. ("possibly, mechanisms driving the angiogenic cascade are differentially regulated depending on the disease pathology")) is not irrelevant to the claimed invention. Griffioen continue to state that the data obtained as of the year 2000 do not allow a definite conclusion about whether inflammation-induced angiogenesis and tumor growth-induced angiogenesis are analogous processes (page 262, column 2, first full paragraph). Thus, the state of the art at the time the instant invention was filed recognizes that angiogenesis inducement in different diseases or conditions may not be the same. The Examiner cited pertinent evidence (Griffioen et al., Simo et al.) to emphasize that the skilled artisan would not be able to predict that the administration of a CRFR2 agonist to an individual with cancer will have the same result (i.e., inhibition of angiogenesis) in an individual with a different condition requiring an inhibition of angiogenesis (i.e., diabetic retinopathy or endometriosis). Undue experimentation would be required of the skilled artisan to determine if angiogenesis could be inhibited in an individual with a condition other than cancer using a CRFR2 agonist.

(iii) At page 10 of the Response, Applicant argues that the cited quotation regarding thrombospondin-1 presented in Griffioen et al. (page 262, left column) describes the effects of this compound on the disease parameters in tumor growth-related angiogenesis as compared to the chronic inflammatory disease arthritis. Applicant contends that the implication of this passage relates to the question of whether it is prudent for a clinician to administer an angiogenesis inhibitor to ameliorate the symptoms of a given disease, not whether or not angiogenesis inhibitors can inhibit angiogenesis in a variety of disease states. Applicant states

that the quoted passage is irrelevant to the question as to whether the present invention provides a sufficient written description and enablement of inhibition of angiogenesis via a CRFR2 agonist in a disease other than cancer.

Applicant's arguments have been fully considered but are not found to be persuasive. First, a *prima facie* case of scope of enablement only under 35 U.S.C. § 112, first paragraph was made in the previous Office Action. Secondly, contrary to Applicant's assertion, the statement in the previous Office Action about thrombospondin-1 (citing Griffioen et al.) is not irrelevant to the claimed invention. Griffioen states that the codependence of angiogenesis and chronic inflammation seems to justify the development of inhibitors of chronic inflammation for specific tumor types and inhibitors of angiogenesis for the treatment of chronic inflammation (page 262, column 2, 1<sup>st</sup> full paragraph). Griffioen teaches that in animal models, thrombospondin-1 inhibits tumor-induced angiogenesis (page 262, column 2, first full paragraph). However, Griffioen also discloses that thrombospondin-1 worsens the disease parameters in adjuvant-induced arthritis (a chronic inflammatory disease). Griffioen concludes that "care should be taken in just extrapolating the knowledge on tumor angiogenesis to the situation of chronic inflammation" (page 262, column 2, first full paragraph). Thus, in view of the state of the art at the time the instant application was filed, the skilled artisan would not be able to predict that the administration of a CRFR2 agonist to an individual with cancer will have the same result (i.e., inhibition of angiogenesis) in an individual with a different condition requiring an inhibition of angiogenesis (i.e., diabetic retinopathy or endometriosis). Undue experimentation would be required of the skilled artisan to determine if angiogenesis could be inhibited in an individual with a condition other than cancer using a CRFR2 agonist.

(iv) At page 11 of the Response, Applicant asserts that the Action has not provided any substantial reason to question the enablement of the present disclosure. Applicant states that in the current case, the element asserted to be lacking is disclosed in the specification and known in the art. Applicant cites *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). Applicant also quotes Griffioen at page 238 and concludes that inhibition of angiogenesis via a CRFR2 agonist in a disease other than cancer could be performed without undue experimentation.

Applicant's arguments have been fully considered but are not found to be persuasive. The Examiner made a *prima facie* showing that the claimed invention lacks enablement and provided sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing (see pages 5-8 of the previous Office Action of 14 May 2008 and points (i)-(iii) above). The Examiner has fully considered all evidence of record and has responded to each substantive element of Applicant's response (see points (i)-(iii) above).

Additionally, although a patent or application need not teach what is well-known in the art, this statement is not a substitute for an enabling disclosure. The courts have stated that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be corrected by asserting that all the disclosure related to the process is within the skill of the art. Reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. See *Genentech v. Novo Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997). The specification of the

instant application is clearly only a starting point for future experimentation for the skilled artisan since there is little or no guidance to indicate that administration of a CRFR2 agonist inhibits angiogenesis in individuals with any condition which is not cancer. The present invention is unpredictable and complex wherein one skilled in the art may not necessarily inhibit angiogenesis in an individual having a pathophysiological condition which is not cancer and undue experimentation would be required by the skilled artisan to determine such.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to inhibit angiogenesis in an individual with a condition which is not cancer by administration of a CRFR2 agonist, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, the contradictory state of the prior art (see Griffioen et al., Simo et al.), and the unpredictability of the effects of a CRFR2 agonist on angiogenesis inhibition in an individual with a condition which is not cancer, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB  
Art Unit 1647  
29 January 2009

/Bridget E Bunner/  
Primary Examiner, Art Unit 1647